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| 10/517,849 | 07/22/2005 | Werner Wessling | R00957US (#90568) | 1323 |

7590 06/08/2009
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| EXAMINER |
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PALENIK, JEFFREY T

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| ART UNIT | PAPER NUMBER |
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1615

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06/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|---|--|
| Office Action Summary | Application No. 10/517,849 | Applicant(s) WESSLING, WERNER | |
| | Examiner Jeffrey T. Palenik | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-35 is/are pending in the application.
- 4a) Of the above claim(s) 9-16, 20 and 22-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 17-19, 21, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

STATUS OF THE APPLICATION

Applicant's amendments and remarks, filed 17 March 2009 regarding the Request for Continued Examination (RCE) of Application N° 10/517,849, are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 2 and 3 have been cancelled.

No new claims have been added.

Claims 1 and 34 have been amended to incorporate the limitations of cancelled claims 2 and 3, thereby providing support for the amendments. The amendments to claims 1 and 34 also remove the polymer limitations of: acacia, starch, starch derivatives, polyethylene oxide polymers, polyethylene glycol, gelatin, collagen, tragacanth and natural gums, in addition to the limitation wherein the polymer matrix is comprised of a polymer which is both water-soluble and swellable in an aqueous medium. Furthermore, claim 34 has been amended to independent form as well as amended to recite "a cannabis oil", which is supported at ¶[000026].

The Examiner acknowledges that no new matter has been added to the claims.

Thus, claims 1, 4-8, 17-19, 21, 34 and 35 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

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PERFECTION OF APPLICANT'S PRIORITY

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The Examiner acknowledges the receipt of the certified foreign translation for German Patent Application 102 26 494.5, filed 14 June 2002. As such, Applicant has perfected their priority requirement and priority is extended to the above noted filing date.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Claims

Applicant's amendment to claim 1, correcting the inadvertent removal of the term "consisting", has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

Rejections under 35 USC 112

Applicant's remarks, as well as the amendments made to claim 34, as discussed above, render moot the new matter rejection, under 35 USC 112, first paragraph. Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 12 November 2008:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 17-19, 21, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (US Pre-Grant Publication No. 2002/0136752).

The instant amended claims are drawn to a film-shaped mucoadhesive composition containing a cannabis extract comprising tetra-hydrocannabinol (THC) and at least one further cannabinoid, said film having a thickness of 0.5 mm or less (claim 1). The polymer administration form is recited as comprising a polymer matrix and representing a percent by weight of the composition (claims 2, 3 and 17). The administration form is recited as comprising a percentage of cannabis extract (claims 4 and 18). The administration form is recited as further comprising additional flavoring and odorous compounds (claims 5 and 19). The thickness of the overall composition is further limited (claims 6 and 21). The administration form is recited as further comprising at least one inactive ingredient (claim 7) and as having multiple layers

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wherein at least one layer contains an active agent (claim 8). New claim 34, as discussed above, does not further limit claim 1 since, cannabis oils, absent a clearer definition, are interpreted in the same scope as cannabis extracts. Claim 35 recites species limitations to cannabinoids.

Whittle et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent (claim 1 and Examples 9). Example 9 expressly teaches a melted mass (i.e. matrix) formulation which serves as a reservoir for two cannabis active ingredients: tetrahydrocannabinol (THC) and cannabidiol (CBD). The formulation expressly teaches the presence of a cannabis extract (e.g. THC) and a cannabinoid compound present, each in the amounts of 5 parts per 90 parts (e.g. about 5.5% by weight). Absent any evidence to the contrary, the units “parts” is interpreted by the Examiner as teaching “percent by weight”. This expressly teaches the instantly claimed limitations of claims 1, 2, 4, 18, 34 and 35. The composition of Example 9 further teaches the instantly claimed a water-soluble polymer limitation of claims 3 and 17 whereby it contains gum Acacia (e.g. a water-soluble natural gum) in the amount of 20 parts per parts (e.g. about 22% by weight). The Example also teaches the instantly claimed odorous substances limitation of claims 5, 7 and 19 whereby the taught composition contains vanillin. The limitations of claim 7 are also expressly taught by both claim 1 and Example 9, which respectively teach the inclusion of an emulsifying agent in the form of glyceryl monoleate. Lastly, Example 9 and Figures 1-4 teach that the composition must not only be able to fit comfortably inside oral cavity, but also conform to a thickness requirement. Example 9 expressly teaches a preferred thickness of 2.5 mm, achieved by rolling out the hot-melted mass into a sheet. Example 11 expressly teaches the

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limitations of the instant claims 1, 2, 4, 8 18, 34 and 35, whereby the mucoadhesive composition comprises both a cannabis extract and a cannabinoid, again THC and CBD, and within the claimed percentages. The limitations of claim 8 are expressly taught in Example 11, which teaches a two-layered composition the first layer of which comprises THC in the amount of 15 parts per about 133 parts (e.g. about 7.5% by weight) and the second layer of which comprises CBD in the amount of 20 parts per about 165 parts (e.g. about 12.1% by weight). The overall composition thus comprises 15 parts per about 298 parts of THC (e.g. about 2% by weight). The overall composition further comprises 15 parts Acacia gum and 100 parts glyogelatin per 298 parts (e.g. about 38.6% by weight) as well as glyceryl monoleate as the emulsifying agent. Example 10, which teaches no specific formulations, serves to further elaborate on the final forms which are applicable to the different Examples, citing specifically that the melted molds may be molded or cast into films.

Though Whittle expressly teaches nearly every aspect of the instantly invention, the teachings do not expressly teach the overall administration form as conforming to the instantly claimed thickness limitations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form, as taught and suggested by Whittle, modify the thickness of the cast film form, and produce the instantly claimed invention.

One of ordinary skill in the art would have been highly motivated to do this because Whittle expressly teaches each of the aforementioned aspects of the instantly claimed invention

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with the exception of conforming said article to the claimed dimensions. Furthermore, as discussed above, in view of Figures 1-4 and Examples 9-10 of the invention practiced by Whittle, it would have been *prima facie* obvious to a person of ordinary skill in the art to optimize the thickness parameter of the administration forms (see MPEP §2144.04 (IV)(B.)) for any number of reasons related to the efficacy or aesthetic aspects of the invention (i.e. to be able to accommodate the variety different oral or buccal locations to which the form will be applied). Thus, absent some demonstration of unexpected results or criticality from the claimed parameters, optimization of any of the thickness parameter would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicant's arguments with regard to the rejection of claims 1,4-8, 17-19, 21, 34 and 35 under 35 USC 103(a) as being unpatentable over the teachings of Whittle et al. have been fully considered but they are not persuasive.

Applicant have amended claims 1 and 34 removing gum acacia from the polymer matrix limitation, thereby alleging that Whittle now fails to teach every feature of the present claims

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since the polymer matrix of the mucoadhesive administration forms as presently claimed are prepared from polymers which are clearly different from the polymers taught by Whittle.

In response, the Examiner respectfully disagrees and submits that in reconsideration of the Whittle reference, it was discovered that Applicant's claims continue to recite hydroxypropyl cellulose, an emulsifying, stabilizing and viscosity modifying polymer, which is expressly taught in Table 2 of Whittle. It is thus considered by the Examiner, in view of the Table and the Examples that the ordinarily skilled artisan would have been motivated to substitute in hydroxypropyl cellulose for acacia as they are taught as being functionally equivalent viscosity modifying polymers. That the polymers listed in the Table are used in gels formed by combining substances of opposite electrical charges, as Applicant points out, is irrelevant given that electrical charge of the polymers is not a limitation which was considered in the rejected claims.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615